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Congress of the United States
House of Representatives
Washington, DC 20515-0913

September 13, 2021

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SUBCOMMITTEES:

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SUBCOMMITTEES:

SPACE AND AERONAUTICS

ENVIRONMENT

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock,

I write to urge you to take every appropriate step within your power to authorize a safe and effective COVID-19 vaccine for children under 12, particularly for our school age children who have returned to in-person learning.

As you know, the pandemic's impact on children has dramatically increased. As of September 2nd, over five million cases were reported in children, representing 15.1 percent of total nationwide cases. This alarming increase in child cases is in large part driven by the lack of an approved vaccine for children, combined with the return of in-person learning. Social isolation, missed school, difficulties finding affordable childcare, and the added stress of the pandemic have profoundly affected families over the past 18 months. Community leaders, health officials, parents, teachers, and school administrators have been working to create safe, in-person learning environments for our children. While there are things we can do right now to keep children safe, including requiring vaccinations for adults who work with children and wearing masks indoors at schools, nothing compares to a safe, effective COVID-19 vaccine.

I understand that the Food and Drug Administration (FDA) has been working hard to approve a COVID-19 vaccine that is safe and effective for children under 12. As you can imagine, parents are eager for the FDA to reach a favorable conclusion as soon as possible, consistent with FDA's gold standard scientific process. At the same time, many are worried that a vaccine may not be available before the end of the calendar year, given reports that the FDA is requesting manufacturers extend and expand their trials. I would urge the FDA to carefully consider the costs and benefits of expanding the trials, rather than using existing data from the initial cohort.

As you know, children are not just at risk of getting the virus. Infected children can spread the virus to other children, teachers, and immunocompromised adults at home. With my home State of Florida struggling with its worst COVID surge to date, and our Governor recklessly playing politics with masks in schools and downplaying the importance of vaccines, there is a devastating cost to delay. In Florida, we have seen pediatric ICUs near capacity, with more than 13,000 additional deaths over the last four months. The downside risk to the rest of the country enduring a wave like Florida is frightening. In short, the delta variant has changed the stakes.

Should the FDA find that existing safety and efficacy data among COVID-19 vaccines in children meets FDA's rigorous standards, issuing an emergency authorization for school aged children under 12 would be prudent. Children need to be in school, and learning in a safe environment. Thank you for your consideration and I am grateful for all of your work to help us achieve this critical goal.

Sincerely,

A handwritten signature in blue ink that reads "Charlie Crist". The signature is fluid and cursive, with the first name "Charlie" and the last name "Crist" clearly distinguishable.

Charlie Crist
UNITED STATES CONGRESSMAN